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Datasheet for the decision of 9 March 2006

Case Number: T 0741/03 - 3.3.04

Application Number: 95917874.0

Publication Number: 0762890

IPC: A61K 38/26

Language of the proceedings: EN

Title of invention:
Treatment of diabetes

Patentee:
London Health Sciences Centre

Opponent:
Novo Nordisk A/S

Headword:
Treatment of diabetes/LONDON HEALTH SCIENCES

Relevant legal provisions:
EPC Art. 54, 84, 113(1), 114(2)

Keyword:
"Main request, auxiliary requests I to IV - novelty (no)"
"Auxiliary requests V to VII - admission into proceedings (yes); clarity (no)"
"Auxiliary request VIII - admission into proceedings (no)"

Decisions cited:
G 0005/83, G 0004/95, T 0794/94

Catchword:
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Beschwerdekammern | Boards of Appeal | Chambres de recours

Case Number: T 0741/03 - 3.3.04

D E C I S I O N
of the Technical Board of Appeal 3.3.04
of 9 March 2006

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 12 May 2003 revoking European patent No. 0762890 pursuant to Article 102(1) EPC.

Composition of the Board:

Chair: G. Alt
Members: B. Claes
G. Weiss

Summary of Facts and Submissions

I. The appeal was lodged by the patent proprietor (appellant) against the decision of the opposition division to revoke European patent no. 0 762 890, titled "Treatment of diabetes", pursuant to Article 102(1) EPC.

II. Claim 1 as granted read as follows:

"1. Use of a peptide comprising a peptide selected from
(a) glucagon-like peptide 1(7-37);
(b) glucagon-like peptide 1(7-36) amide; and
(c) an effective fragment or analogue of (a) or (b)
in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal."

III. The patent was opposed under Article 100(a) EPC, lack of novelty (Article 54 EPC), lack of inventive step (Article 56 EPC), non-patentable subject-matter by virtue of Article 52(4) EPC, and under Article 100(b) EPC.

IV. During the opposition proceedings the patent proprietor defended its patent on the basis of a main request corresponding to the claim as granted and auxiliary requests I to III.

Claim 1 of these auxiliary requests I to III, respectively, read as follows:

"1. Use of a peptide comprising a peptide selected from
(a) glucagon-like peptide 1(7-37);
(b) glucagon-like peptide 1(7-36) amide; and

(c) an effective fragment of (a) or (b)
in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal."

"1. Use of a peptide comprising a peptide selected from
(a) glucagon-like peptide 1(7-37);
(b) glucagon-like peptide 1(7-36) amide; and
(c) an effective fragment of (a)
in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal."

"1. Use of a peptide comprising a peptide selected from
(a) glucagon-like peptide 1(7-37);
(b) glucagon-like peptide 1(7-36) amide;
in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal."

V. The opposition division held that the main request and auxiliary requests I and II did not comply with the requirements of Article 83 EPC. The opposition division reasoned that the person skilled in the art did not have the necessary information to carry out the part of the subject-matter of the claims relating to the use of **fragments and analogues** of a glucagon-like peptide 1 in the preparation of a medicament.

The claims of the third auxiliary request were not allowable because their subject-matter was found to lack of inventive step in view of document D3 (The New England Journal of Medicine, (1992) vol. 326, no. 20, pages 1316-1322, Gutniak, M. et al.) as it suggested the use of glucagon-like peptide 1 in the treatment of type I diabetes.

VI. With the statement of grounds of appeal the appellant requested as a main request to set aside the decision of the opposition division and to maintain the patent as granted. Further, he filed auxiliary requests I to IV.

VII. In a communication the board informed the parties of its opinion that the subject-matter of claim 1 of all of the auxiliary requests I to IV lacked clarity. Further comments on substantive issues were not made.

VIII. The appellant filed revised auxiliary requests I to IV one month before the oral proceedings.

Claim 1 of the revised auxiliary requests I to IV, respectively, read as follows:

"1. Use of a peptide selected from the group consisting of:
(a) glucagon-like peptide 1(7-37);
(b) glucagon-like peptide 1(7-36) amide; and
(c) an effective fragment of (a) or (b)
in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal."

"1. Use of a peptide selected from the group consisting of:
(a) glucagon-like peptide 1(7-37);
(b) glucagon-like peptide 1(7-36) amide; and
(c) an effective fragment of (a)
in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal."

"1. Use of a peptide comprising a peptide selected from the group consisting of:
(a) glucagon-like peptide 1(7-37); and
(b) glucagon-like peptide 1(7-36) amide
in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal."

"1. Use of insulin and a peptide selected from the group consisting of:
(a) glucagon-like peptide 1(7-37); and
(b) glucagon-like peptide 1(7-36) amide;
in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal."

IX. With the letter dated 2 March 2006, i.e. one week before the oral proceedings, auxiliary request V was filed in response to further written submissions by the opponent (respondent). Claim 1 of this request read as follows:

"1. Use of a peptide selected from the group consisting of:
(a) glucagon-like peptide 1(7-37);
(b) glucagon-like peptide 1(7-36) amide; and
(c) an effective fragment of (a) or (b)
in the preparation of a medicament for improving glycemic control in mammals with Type I diabetes."

X. Oral proceedings were held on 9 March 2006.

First, the parties were heard on the issue of novelty. Then, in reaction to the announcement of the board that the subject-matter of claim 1 of the main request and of auxiliary requests I to IV lacked novelty, the

appellant's representative Mr Barz (hereinafter abbreviated as "Mr B.") filed a letter from the patent proprietor authorizing Mr B. to subauthorize Mr Harding (hereinafter abbreviated as "Mr H."), a professional representative having attended the oral proceedings as a member of the public. At the same time, Mr B. submitted a letter in which he sub-authorised Mr H. to represent the appellant.

Subsequently, Mr H. requested to be allowed to plead on the issue of novelty with regard to the main request and auxiliary requests I to IV.

XI. Further auxiliary requests VI and VII were submitted during the oral proceedings, as well as a final auxiliary request VIII. Claim 1 of these requests respectively, read as follows:

"1. Use of a peptide selected from the group consisting of:
(a) glucagon-like peptide 1(7-37);
(b) glucagon-like peptide 1(7-36) amide; and
(c) an effective fragment of (a) or (b)
in the preparation of a medicament for improving glycaemic control in mammals with Type I diabetes and avoiding hypoglycemia."

"1. Use of a peptide selected from
(a) glucagon-like peptide 1(7-37); and
(b) glucagon-like peptide 1(7-36) amide;
in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal, wherein the mammal is in the remission phase of Type I diabetes having residual endogenous insulin secretion capacity."

"1. Use of a peptide selected from
(a) glucagon-like peptide 1(7-37); and
(b) glucagon-like peptide 1(7-36) amide;
in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal, wherein the mammal is in the remission phase of Type I diabetes."

XII. The appellant's arguments, as far as they are relevant for the present decision, may be summarized as follows:

Request of the sub-authorized representative for the appellant to plead on novelty of the claims of the main request and auxiliary requests I to IV

Since a new sub-authorized representative had been appointed during the oral proceedings, he should have the right to add further comments on novelty.

Novelty

Document D3 did not impair the novelty of the subject-matter of claim 1 of the main request and auxiliary requests I to IV for several reasons:

Firstly, the document explicitly only drew the conclusion that glucagon-like peptide 1(7-36) amide (hereinafter referred to as "GLIP") was useful in diabetes type II treatment, but did not mention that it was likewise useful in the treatment of type I diabetes.

Secondly, the delaying effect of GLIP on gastric emptying was known and was appreciated in document D3. Document D3 only disclosed a single administration GLIP

after a single meal to a subject suffering from type I diabetes. Therefore, no conclusions could be made on whether or not the low blood glucose levels after the meal and after the administration of GLIP were entirely due to the delay of gastric emptying or not. If the blood glucose lowering effect was due to a complete retention of the meal in the stomach, then this lowering effect could not be taken as an indication of a true medical treatment because the non-physiological retention of nutrients could not seriously be considered useful in the treatment of diabetes.

Thirdly, the disclosure of a single administration of GLIP could not be regarded as a treatment because, in the context of diabetes, "treatment" meant "control" of the blood sugar level. This implies that in order for document D3 to be novelty-destroying more than one administration of a medicament ought to have been disclosed.

Fourthly, document D3 disclosed (i) a flawed experiment and ii) results which were (a) either not relevant for the treatment of Type I diabetes, (b) which demonstrated changes within the error margin or (c) which even showed a negative influence on a Type I diabetes related parameter.

Admission into the proceedings of auxiliary requests V to VII

None of the amendments to the claims of these requests rendered the claims unclear. They had furthermore a basis in the description and did not change the case. Therefore, the requests should be admitted.

Auxiliary requests V and VI

Article 84 EPC

The term "glycaemic control" was mentioned in the description of the patent and it was clear what it meant, namely up and down regulation of blood sugar levels.

Auxiliary request VII

Article 84 EPC

The term "remission phase" was used in the patent and moreover well-known in the art. Therefore, a clarity-problem could not arise.

Admission into the proceedings of auxiliary request VIII

No extra words had been added. Thus, the complexity of the case was not increased. Moreover, it should be allowed to refine the claims in response to the board's positions in relation to the earlier requests.

XIII. The respondent's arguments, as far as they are relevant for the present decision, may be summarized as follows:

Representation

In view of decision G 4/95 it was within the discretion of the board to allow oral submissions by persons other

than the initially appointed professional representative.

Request of the sub-authorized representative for the appellant to plead on novelty of the claims of the main request and auxiliary requests I to IV

After having heard the board's preliminary opinion on the novelty of the claims of the main request and auxiliary requests I to IV, the authorized representative had answered the board's question whether he had any further comments on the issue of novelty in the negative and thus had waived any right for further comments.

Main request, auxiliary requests I to IV

Novelty

Diabetes was a metabolic disorder characterized by a too high blood glucose level. Therefore, a treatment of diabetes was carried out if the blood glucose level was lowered in a subject suffering from diabetes.

Document D3 disclosed, on page 1317, the intravenous administration of insulin combined with GLIP to Type I diabetes patients. The same treatment was disclosed in the patent in paragraph [0027]. The last paragraph in the right-hand column on page 1318 and Table 2 disclosed that these procedural steps led to the desired effect.

Admission into the proceedings of auxiliary requests V to VII

If a late-filed request was to be admitted, it had to be prima facie allowable, constitute a serious attempt to overcome an objection and be easy to examine. Here, the new features were neither clear nor were they suited to overcome the novelty objection. Moreover, seeing that the introduced features were not taken from the claims, the amendments were substantial, and therefore difficult to examine.

Auxiliary requests V and VI

Article 84 EPC

Without the indication of a reference point the term "improving" was ambiguous because the skilled reader could not know whether or not a change in the blood glucose level was to be regarded as an improvement of the glycaemic control.

Auxiliary request VII

Article 84 EPC

The term "residual" was not clear because it did not unambiguously define the amount of "endogenous insulin" that was secreted. Hence the claim did not clearly define the patient group to be treated.

Admission into the proceedings of auxiliary request VIII

At such a late stage no more requests should be admitted.

XIV. Requests

The appellant (patent proprietor) requested that the decision under appeal be set aside and that the patent be maintained as granted (main request), or, alternatively, on the basis of the auxiliary requests I to IV submitted with letter dated 8 February 2006, or of the auxiliary request V submitted with letter dated 2 March 2006 or of the auxiliary requests VI, VII and VIII filed at the oral proceedings.

The respondent (opponent) requested that the appeal be dismissed.

Reasons for the Decision

Representation

1. Mr H. is a professional representative pursuant to Article 134(1) EPC and is not a member of Mr B.'s association. Since decision G 4/95 (see point 1 of the Reasons; EPO OJ 1996, 412) deals with the entitlement of persons who are **not** qualified under Article 134 EPC to speak at oral proceedings, the principles set out therein do not apply here.

2. In view of the documents submitted at the oral proceedings (see section X above) the board is satisfied that (i) Mr B. was authorized to sub-authorize Mr H. and that (ii) Mr H. had been correctly sub-authorized by Mr B.

Hence, the board decided that Mr H. was entitled, together with Mr B., to act for the appellant at the oral proceedings.

Request of the sub-authorized representative for the appellant to plead on novelty of the claims of the main request and auxiliary requests I to IV

3. In dealing with the appellant's request for Mr H. to add further comments on the issue of novelty, the question arose whether the appellant's authorized representative, Mr B., had or had not been given sufficient time for pleading on novelty, seeing that if this question had to be answered in the negative, the sub-authorized representative, Mr H., had to be allowed to present further comments on novelty pursuant to Article 113(1) EPC.

3.1 The circumstances at the oral proceedings were as follows: The novelty of the subject-matter of claim 1 was challenged on the basis of document D3. Both, the appellant's representative and the respondent's representative were given two opportunities to present their comments. After these two rounds the board heard the inventor and a person accompanying the appellant. After deliberation the board announced its opinion that the subject-matter of the claims of the main request and auxiliary requests I to IV lacked novelty in view

of document D3. Since the opposition division had given a positive decision on the issue of novelty in relation to document D3 and since the board in its communication had not made any observations on the issue, the board deemed it appropriate after having announced its position and although the contents of document D3 had already been extensively discussed, to ask the appellant's representative again whether he had any further comments. He had none.

At that point in time, in the board's judgement, the appellant had been given sufficient opportunity to present comments on the issue of novelty. Accordingly, the board deemed the requirement of Article 113(1) EPC fulfilled.

In view of the above considerations, the board refused the request of the sub-authorized representative Mr H. to plead on novelty of the claims of the main request and auxiliary requests I to IV. The board notes that this conclusion is not related to the fact that a sub-authorized representative had been newly appointed **during** the oral proceedings.

Main request

Article 54 EPC

4. Claim 1 is directed to the "use of a peptide comprising a peptide selected from (a) glucagon-like peptide 1(7-37),(b) glucagon-like peptide 1(7-36) amide and (c) an effective fragment or analogue of (a) or (b) in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal".

5. Document D3 discloses investigations on the antidiabetogenic effect of glucagon-like peptide 1(7-36) amide in normal subjects and in patients with non-insulin dependent diabetes mellitus (NIDDM), also known as Type II diabetes, and insulin-dependent diabetes mellitus (IDDM), also known as Type I diabetes. This is also reflected in the title of this document reading: "Antidiabetogenic effect of glucagon-like peptide-1 (7-36)amide in normal subjects and patients with diabetes mellitus".

6. According to decision G 5/83 (OJ EPO 1985, 64) a claim drafted in a so-called "second medical use" format overcomes the non-patentability of a method of treatment of the human or animal body by therapy resulting from Article 52(4) EPC. Hence, claim 1, being in that format, is in effect relating to a method of treatment of Type I diabetes in a mammal with one of the compounds specified in the claim. Consequently, for document D3 to be detrimental to the novelty of the subject-matter of claim 1, the skilled person should be in a position to clearly and unambiguously derive from it the disclosure of a treatment of Type I diabetes in a mammal with glucagon-like peptide 1(7-36) amide.

7. In order to determine the anti-diabetogenic properties of glucagon-like peptide 1(7-36) amide (hereinafter referred to as "GLIP"), the authors of document D3 carried out the following experiments: Patients of all three groups (see point 5 above) received an infusion of either GLIP or saline. At time zero of the infusion period the patients received a standard lunch. Blood samples were obtained at time points -30, 0, 15, 30, 90,

120, 150 and 180 min relative to time point of GLIP administration (page 1317, left-hand column). The effect of GLIP was measured on, inter alia, the postprandial blood glucose concentrations, plasma free insulin, glucagon, somatostatin and the exogenous insulin requirement.

7.1 Table 2 summarizes results of measurements of various diabetes-related parameters. In the first line, blood glucose concentrations of all three patient groups are reported after saline or GLIP infusion. In patients with Type I diabetes the blood glucose level was at 64.2 mmol/liter with GLIP infusion and at 132.3 mmol/liter with saline infusion.

7.2 This result is commented in document D3, inter alia, as follows:

(a) Page 1318 to 1319: "In the patients with IDDM, the infusion of GLIP **decreased the postprandial increase in the blood glucose** and plasma free insulin concentrations (Fig. 3)." (emphasis added).

(b) Page 1320, left-hand column: "...because of the antidiabetogenic effects of the peptide, **the postprandial blood glucose concentrations were lower during GLIP administration.**" (emphasis added).

From the above statements the board concludes that document D3 discloses an effect of GLIP on several diabetes-relates parameters, amongst them, **the reduction of the postprandial increase in the blood glucose level.**

8. It is undisputed among the parties that the main symptom of Type I diabetes (and also of non-insulin dependent diabetes mellitus or NIDDM) is too high a blood glucose level (appellant's letter dated 28 January 2005 and respondent's argumentation, see section XIII above).

Accordingly, the main treatment of diabetes mellitus, including that of Type I diabetes, consists in the application of medicaments normalizing the blood glucose level.

This conclusion is confirmed in the patent in suit in paragraph [0002] - "The recent findings of the Diabetes Control and Complications Trial (DCCT) carried out by the U.S. National Institute of Health have emphasized the importance of doing everything possible to normalise blood glucose levels in diabetics to avoid or delay micro-vascular damage." - and it is also shared by the parties (respondent's argumentation, see section XIV above and appellant's letter of 28 January 2005 where it is stated in the context of the question how the activity of fragments of GLIP is determined: "**The effect to be demonstrated [...] is the regulation of glucose levels after ingestion of a meal**. [...] This effect is simply tested in vivo similar to the peptides of the invention as described in the examples of the opposed patent. A skilled artisan would simply administer a fragment or analogue of GLIP or glucagon-like peptide 1(7-37) to a suitable animal or human [...]. **Blood levels of glucose**, glucagon and insulin can be readily assayed by standard methods [...]. **These measured levels would then determine the suitability of**

the claimed fragments or analogues in the treatment of Type 1 diabetes."; emphasis added)

9. As set out in point 7 above, document D3 discloses the administration of GLIP to human patients suffering from Type I diabetes. The increase of the glucose concentration in the blood after a meal is lower upon administration of GLIP than upon administration of saline (see points 7.1 and 7.2 above).

Hence, the board concludes that the skilled person would derive from document D3 the disclosure of a treatment of Type I diabetes with GLIP.

10. The appellant argues that document D3 does not disclose the treatment of Type I diabetes with GLIP because the authors of document D3 explicitly only draw the conclusion that GLIP may be useful in the treatment of patients with NIDDM - "GLIP has an antidiabetogenic effect, and it may therefore be useful in the treatment of patients with NIDDM" (last sentence of the abstract) - but do not make comparable suggestion with regard to the treatment of Type I diabetes.

10.1 However, the board considers that the lack of an explicit statement about the usefulness or non-usefulness of GLIP in the treatment of Type I diabetes can, even in the light of a positive statement with regard to the usefulness of GLIP in the treatment of NIDDM, not automatically be interpreted to the effect that GLIP is not useful in the treatment of Type I diabetes. Hence, the lack of an explicit conclusion on the treatment of Type I diabetes with GLIP would not cast doubt on or even reverse the positive results

reported in document D3 as set out in points 7, 7.1 and 7.2 above.

11. In a further line of argumentation as to why document D3 does not disclose a treatment of Type I diabetes the appellant submits that at the relevant date of the patent the skilled person is aware of (see also document D3, page 1320, right-hand column), that GLIP causes the prolongation of gastric emptying by delaying the digestion and absorption of food following a meal with the consequence that the postprandial increase in glucose level is lowered. In the course of the experiments disclosed in document D3 one single meal was given to the patients and the blood glucose level was measured once after that meal. Hence, from this experimental set-up it is not derivable whether or not GLIP blocks the transit of nutrients to such an extent that normal nutrition would not be possible. In the former case the administration of GLIP would be, so-to-speak, "toxic" and could therefore not be considered as a treatment.

11.1 However, the board observes that a decision on whether subject-matter is novel or not is not to be made on considerations of probability (Case Law of the Boards of Appeal of the European Patent Office, 4th edition, 2006, I.C.2.1). Document D3 does not contain any statements from which the skilled person could derive the exact nature of the effect of GLIP on the transit time. On the contrary, it is explicitly said in document D3 (emphasis added): "The infusions of GLIP attenuated the postprandial increase in blood glucose concentrations, suggesting that the peptide **may** prolong the transit time of nutrients in the gastrointestinal

tract. GLIP is known to prolong gastric emptying, but its effect on transit time in the intestine **has not been studied**." Hence, the possibility of a deleterious influence of GLIP on the transit of nutrients is hypothetical and can therefore not be taken account in the evaluation of novelty.

11.2 Moreover, the board notes that document D3 rather seems to provide evidence that there is no such severe delay in gastric emptying. Firstly, if there was one, it would concern the patients of all study groups treated with GLIP. Then however, the author's positive remarks on the treatment of NIDDM patients with GLIP would be questionable. Secondly, on the basis of Table 2, a possible effect of GLIP on the transit time could rather than in Type I diabetes patients be assumed to be present in normal subjects and NIDDM patients because, the blood glucose level after GLIP administration in the latter groups seems to be remarkably low compared to the level after saline administration: **153.8** nmol/liter 210 min after saline versus **9.2** nmol/liter 210 min after GLIP in normal subjects; **133,0** nmol/liter 210 min after saline versus **3.3** nmol/liter 210 min after GLIP in NIDDM patients; **132.3** nmol/liter 210 min saline versus **64.2** nmol/liter 210 min after GLIP in type I patients).

11.3 Finally, the board notes that the patent in suit itself provides evidence that the effect of GLIP on gastric emptying is not so pronounced as assumed by the appellant for the sake of argument.

12. The appellant moreover argues that "treatment" of diabetes in fact means "control" of the blood sugar

level, which means that a medicament used for the treatment of diabetes must be safe for an ongoing administration, i.e. relative to several meals. The disclosure in document D3 of a **single** administration of GLIP in relation to a single meal, even if this administration has a positive effect on the blood sugar level, is no evidence that GLIP is appropriate to "control" the blood sugar level.

12.1 Claim 1 relates to the use of GLIP in the "preparation of a medicament for use in the **treatment** of Type I diabetes". The minimum number of applications of a compound covered by the term "treatment" is one. The appellant's argument implies that this is not the definition to be applied in the context of the patent.

12.2 The board cannot concur with this argument, however, because a definition of the term "treatment" deviating from the generally recognized one is neither explicitly nor implicitly derivable from the patent in suit. On the contrary, in the six examples disclosed in the patent/diabetes-related parameters, as for example, the blood levels of glucose, were determined after one single meal and one application of GLIP. Hence, in the board's judgement, there is no basis for a more restricted interpretation of the term "treatment" in the context of the present patent. Therefore, the treatment referred to in claim 1 encompasses a single administration of GLIP.

13. Finally, the appellant has drawn the board's attention (i) to an experiment disclosed in document D3 which in the appellant's view is flawed (determination of insulin sensitivity) and the result of which could

therefore not be taken into account and (ii) to results which, in the appellant's view, are (a) either not relevant with regard to the treatment of Type I diabetes (stimulation of endogenous insulin) because the parameter only concerns NIDDM or (b) because the change of the parameter is within the error margin (increase in glucose utilisation) or (c) demonstrate a less positive influence on one of the Type I diabetes disease-related parameters (glucagon) and would therefore have shed doubt on the suitability of GLIP as a medicament for the treatment of Type I diabetes.

13.1 However, even if, for the sake of argument, the appellant's views on the interpretation of the experiment and the results were to be accepted, these "negative" indications would not change the fact that document D3 disclosed a treatment of Type I diabetes by virtue of the lowering of the blood glucose level after the treatment by GLIP (see above). Hence, this argument too is not convincing.

14. In view of above considerations, the board concludes that the skilled person clearly and unambiguously derives from document D3 the disclosure of a treatment of Type I diabetes in a mammal with glucagon-like peptide 1(7-36) amide. Therefore, the subject-matter of claim 1 does not fulfil the requirements of Article 54 EPC.

Auxiliary Requests I to IV

15. Part (b) of claim 1 of each of auxiliary requests I to IV is, similarly to part (b) of claim 1 of the main request, directed to the use of glucagon-like peptide

1(7-36) amide in the preparation of a medicament for use in the treatment of Type I diabetes in a mammal. Hence, document D3 anticipates the subject-matter of claim 1 of auxiliary requests I to IV, respectively, for the reasons set out above in points 4 to 14.

16. Therefore, the claims of auxiliary requests I to IV do not fulfil the requirements of Article 54 EPC.

Auxiliary Requests V, VI and VII

Admission into the proceedings of auxiliary requests V, VI and VII

17. Auxiliary request V had been filed one week before the oral proceedings in response to a written submission by the respondent. Auxiliary requests VI and VII were filed during the oral proceedings in response to the board's announcement of its opinion on the novelty of the subject-matter of the claims of the main request and auxiliary requests I to IV.

17.1 Whether late-filed requests are not admitted into the proceedings is a matter within the discretion of the board (Article 114(2) EPC), in the light of the particular circumstances of the case (see for example decision T 794/94 of 17 September 1998).

17.2 In the present case the opposition division had decided that the document D3 did not disclose the treatment of Type I diabetes. In its response to the statement of the grounds of appeal the respondent maintained its objection that document D3 was novelty-destroying. In its communication the board did not comment on the

relevance of document D3. At the oral proceedings the board refused the main request and auxiliary requests I to IV for lack of novelty over the disclosure of document D3. Under these circumstances the board deemed it appropriate to give the appellant a further opportunity to defend his patent.

Likewise, in allowing the requests the board did not see any danger of the respondent's right to be heard being violated because the amendments seemed, at least prima facie, not to be substantial, although the concerned features are taken from the description. Finally, the late-filing of auxiliary requests VI and VII is to be seen here as a reaction to the board's announcement of its opinion on novelty so that a procedural abuse has not occurred.

Therefore, the board did not make use of its discretion pursuant to Article 114(2) EPC and admitted auxiliary requests V to VII into the proceedings.

Auxiliary request V

Article 84 EPC

18. The feature "improving glycaemic control" which was added to claim 1 was not contained in any of the granted claims. Therefore, it is open to examination of the requirements of Article 84 EPC.

18.1 According to the description of the patent the term "glycaemic control" means "normalisation of blood glucose levels" in a diabetes patient (see paragraph [0002]).

It is further stated in that paragraph that "intensified insulin therapy has been shown by the trial to improve glycaemic control ...", i.e. a modification of the standard insulin therapy provided an improvement of glycaemic control. Hence, in the context of the patent, the term "improving" is used to describe an improvement over a previous glycaemia controlling therapy.

18.2 It can be taken, for example, from paragraphs [0026], [0027] and [0031] of the description of the patent that GLIP may be used alone or in combination with insulin for treating Type I diabetes. It is stated in paragraph [0026]: "Some remission phase Type I subjects may be sufficiently controlled by administration of GLIP alone." Hence, the patent envisages the administration of GLIP to patients having or not having had a previous treatment for glycaemic control.

18.3 Claim 1 lacks a feature pertaining to the characterisation of the state of treatment of the patient to which GLIP is administered. Consequently, in the light of the description, claim 1 is interpreted as being directed to the use of GLIP as defined in parts (a) to (c) of the claim in the preparation of a medicament for improving glycaemic control in mammals with Type I diabetes, these mammals being treated **or not** for glycaemic control by a medicament different from GLIP.

18.4 As noted above, in the patent the occurrence of an improvement is determined by reference to a previous treatment regimen for achieving glycaemic control.

Therefore, in the judgement of the board, as far as claim 1 relates to already treated Type I diabetes patients, the skilled person does not have problems in determining what is meant by "improving" the glycaemic control with GLIP.

In contrast, however, if GLIP is administered alone, glycaemic control is caused by GLIP. The patent is however silent on which "improvement" can be caused by GLIP under these circumstances or in relation to which condition it should be determined. Hence, the board concludes that, as far as the claim relates to previously "untreated" patients, i.e. to patients receiving GLIP alone, it is unclear to the skilled person what "improving" glycaemic control means.

18.5 Consequently, claim 1 does not fulfil the requirement of clarity pursuant to Article 84 EPC.

Auxiliary request VI

Article 84 EPC

19. Claim 1 of this request differs from claim 1 of the previous request by the addition of the term "and avoiding hypoglycaemia" at the end of the claim. This term has not been part of the granted claims and is therefore open to examination under Article 84 EPC.

19.1 "Hypoglycaemia" is mentioned in the patent in suit as one of the complications of insulin therapy (paragraphs [0002] and [0029]. Hence, the expression "and avoiding hypoglycaemia" relates to the use of GLIP in combination with another medicament (point 18.2 above).

Therefore, this term in the claim is not suited to remove the uncertainties about the meaning of "improving" in the case of patients not receiving a combination therapy, i.e. patients receiving GLIP alone.

Hence, the reasoning given in point 18 applies also to claim 1 of this request.

19.2 Consequently, claim 1 of auxiliary request VI does not comply with he requirements of Article 84 EPC.

Auxiliary request VII

Article 84 EPC

20. The expression "wherein the mammal is in the remission phase of Type I diabetes having residual endogenous insulin secretion capacity" contained in claim 1 of this request was not a part of the granted claims and is therefore open to examination under Article 84 EPC.

20.1 In paragraph [0016] of the patent subjects in the remission phase are characterized as having "**substantial** remaining endogenous insulin secretion"(emphasis added). In claim 1, in contrast, subjects in the remission phase are characterized by "having **residual** endogenous insulin secretion capacity" (emphasis added). This second definition appears as well in the description in paragraph [0026]. Accordingly, the affiliation of a patient to the group of remission phase patients is made on the basis of two different levels of produced insulin - "residual" and "substantial" - in the description. It is not therefore clear to the skilled person whether the term "residual"

in claim 1 means "residual" or "residual, substantial". In view of the above inconsistency, the term in claim 1 defining the minimum amount of insulin to be produced by a patient in order to be regarded as a patient in the remission phase of Type I diabetes is not clear and consequently, the group of patients to which GLIP is administered is not clear too.

20.2 Moreover, even if there was no such inconsistency in the definition of minimum amount of insulin to be produced by a patient in order to be regarded as a patient in the remission phase of Type I diabetes, there is, in the board's judgement, a lack of clarity, since none of the terms "residual" and "substantial" has a precise meaning, either as such or on the basis of the patent in suit.

20.3 Consequently, claim 1 of auxiliary request VII does not fulfil the requirements of Article 84 EPC.

Admission into the proceedings of auxiliary request VIII

21. Proceedings before the EPO are not only governed by the principle of fairness, but also by the objective to conduct them in an efficient and effective way. From this second procedural principle follows, inter alia, that during appeal proceedings, firstly, there is no right to file a succession of new requests in substitution for requests found inadmissible or unallowable by the board and, secondly, that the criterion of clear allowability of a request gains weight the later a request is submitted during the proceedings (see for example decision T 794/94, supra).

22. Auxiliary request VIII was filed after the board had already admitted three late-filed requests into the proceedings and had announced its opinion on them i.e. auxiliary request VIII is filed at a very late stage of the proceedings. In order to convince the board to accept such a request even at a very late stage, it should at least clearly meet the requirements under Articles 84 and 123 EPC.

22.1 Claim 1 of auxiliary request VIII differs from claim 1 of auxiliary request VII in that the expression "having residual endogenous insulin secretion capacity" is deleted.

22.2 The deletion of the expression "having residual endogenous insulin secretion capacity" is, in the board's judgement, not suitable to overcome the clarity objection raised with regard to claim 1 of the previous request. The term "remission phase" in claim 1 of this request is interpreted by the skilled person in the light of the definitions given to it in the description. Therefore, the skilled person is confronted with the same unclear situation as referred to in relation of claim 1 of auxiliary request VII. Consequently, claim 1 of auxiliary VIII is not clear for the reasons given in point 20 above.

Therefore, the board cannot consider auxiliary request VIII to be a clearly allowable request, such as might be admitted into the proceedings at such a late stage, and consequently exercised its discretion under Article 114(2) EPC not to admit this claim request into the proceedings.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chair:

P. Cremona G. Alt